# Internal Auditor Training
# July 15-16 2019

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# Internal Auditor Agenda

**1**   **Day 1 – Introductions, QMS Auditing Mission, Why Audit, Who should Audit, Auditor Traits, Auditor Connizance, Proficiencies, Responsibilities, Standard Types, Aerospace Overview or Requirements, Definitions / Key Terms, AS9100 Key Requirements, Audit Basics, Audit Phases**

**2**   **Day 2 – Audit Implementation, Interview Techniques, Objective Evidence, PEARs, Closing Meeting, Report Writing, Corrective Action (5 why), Dirty Dozen, Follow Up and Closure**

# QMS Auditing Mission

Quality is the fulfillment of expectations. The purpose of the QMS Auditing is **NOT** to **police** or **search for discrepancies** or **blame** but to ensure fulfillment of expectations by gathering **objective evidence** of **compliance** through measuring, analyzing, and reporting data. Auditing helps to monitor our processes and any **corrective** and **preventive** actions to ensure **continuous improvement** of our entire Quality Management System.

# Why Do Internal Audits?

➢ To determine implementation **effectiveness** of one's own quality system

➢ To determine the conformance or nonconformance of quality system elements to specified **contractual** requirements

➢ To determine the conformance or nonconformance of quality system
➢ elements to specified **interested party** requirement including regulatory

➢ To provide a basis for **improvement** of your quality system

➢ To achieve third party **registration**

➢ To satisfy **customer** requirements

➢ To increase **profits**

# Ensure value added QMS internal audits

- **Proper Auditor Training**
  - ➤ Selection based on job performance, competencies, and appropriate personality traits and company / process knowledge
  - ➤ Classroom training and / or tests
  - ➤ Observation of audit skills and personal interactions

# Who Should Do Internal Audits

➤ People who have an interest in auditing, organizational and personal improvement, growth

➤ People who are knowledgeable in the subject matter / audit topic

➤ People who are proficient in their own processes and have a great work ethic

➤ People with good people skills

# Auditor Traits

## POSITIVE TRAITS

- Friendly
- Approachable
- Reliable
- Tactful
- Open Minded
- Good Communication Skills
- Business Casual Dress

## NOT SO POSITIVE TRAITS

- Stern expressions /demeanor
- Know it all
- Judgmental / argumentative / combative
- Procrastinator
- Closed minded
- Inappropriately dressed

# Auditor Cognizance / Familiarity

➢ **Check Documentation (From PO to CofC)**

➢ **Review Previous Results to Ensure Improvement, Lessons Learned, Approved Suppliers, Training etc.**

➢ **Verify Compliance to External Provider Requirements are being Met.**

➢ **Interview Process Owners, AND All Levels of Workers**

➢ **Human Factors – Dirty Dozen**

➢ **Observe People Doing / Following Processes**

➢ **Declare and Document any Findings, NCRs**

# Auditor Proficiencies

> **Internal Processes being audited**

> **Risk Management**

> **Audit Processes**

> **Human Factors – Dirty Dozen**

> **Corrective Action Process**

> **Audit Performance Training**

> **Root Cause Analysis**

> **AS9100D**

# Auditor Responsibilities

## LEAD AUDITOR

- **Determine audit dates with management**

- **Select team auditors**

- **Develop schedule**

- **Send documents to be audited to team**

- **Gather all OE and data from team auditors**

- **Publish reports and CARs**

## TEAM AUDITOR

- **Attend entire audit**

- **Ensure Lead has all OE and complete OE Report – before leaving audit site**

- **Ensure issues found are clearly communicated to Lead as well as responsible party.**

- **Be available for any needed clarifications, additional information etc.**

# Key Terms and Definitions

**3.1 Counterfeit Part** - An unauthorized copy, imitation, substitute, or modified part (e.g., material, part, component), which is knowingly misrepresented as a specified genuine part of an original or authorized manufacturer.

**3.2 Critical Items** - Those items having significant effect on the provision and use of the products and services; including safety, performance, form, fit, function, producibility, service life, etc.; that require specific actions to ensure they are adequately managed.

**3.3 Key Characteristic** - An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

**3.4 Product Safety** - The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

**3.5 Special Requirements** - Those requirements identified by the customer, or determined by the organization, which have high risks of not being met, thus requiring their inclusion in the operational risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity.

# Aerospace Standards

**AS9100D – Manufacturing**

This standard is intended for use by organizations that design, develop, or provide aviation, space, and defense products and services; and by organizations providing post-delivery activities, including the provision of maintenance, spare parts, or materials for their own products and services.

**AS9120B – Distribution**

Organizations that procure parts, materials, and assemblies and resells these products to a customer in the aviation, space, and defense industry should use the IAQG-developed 9120 standard. This includes organizations that procure products and split them into smaller quantities, as well as those that coordinate a customer or regulatory controlled process on the product.

**AS9110C – Maintenance and Repair**

Organizations whose primary business is providing maintenance or continuing airworthiness management services for civil or military aviation articles and products; and original equipment manufacturers with maintenance, repair, and overhaul operations that are operated autonomously, or that are substantially different from their production operations; should use the IAQG-developed 9110 standard.

# Overview of AS9100D Requirements

➤ Context of the Organization – needs and expectations of interested parties, scope, QMS and its processes

➤ Leadership – quality policy, roles/responsibilities

➤ Planning – RISK, objectives, planning

➤ Support – resources, awareness, environment, monitoring/measuring, org. knowledge, communication, documented information control

➤ Operation –planning, risk mgmt, requirement (and changes of rqmts) of products and services, configuration mgmt, prevention of counterfeit parts, Design & Development, ctrl of external providers

➤ Performance Evaluation – Monitoring, Measuring, Analysis, Eval, cust. sat., IA, MR,

➤ Improvement – NC, CA, Cont. Improvement

# Audit Phases

➤ Planning – Schedule, Notification, Plan, Document Review/Preparation

Documents to Review: The AS9100D Standard, Customer Requirements, Safety (OSHA) Standard as well as any required regulatory requirements. And your own processes, SOPS, etc.

# Audit Implementation

- Opening Meeting – who is invited?, what is discussed?, Escorts – do we need them?,

- Interviewing – putting auditee at ease, let them tell you what they do and ask questions as they go through their task, questioning techniques,

- Objective Evidence - gathering and documentation of objective evidence – how many samples do I need?

**DAY 1 Completed**

# Interviewing Techniques

➢ Ask open ended questions: Why? Who? What? When? How? Where?

➢ Don't ask all questions, observe - - A LOT

➢ Be prepared to go beyond prepared questions – Follow you intuition

➢ Be sure to get answers from people who are actually doing the work

➢ Tell me how?

➢ Show me how?

➢ Pregnant Pause

➢ In the end make sure the client knows and has an opportunity to address any concerns

# Types of Questions

➢ Open-ended:  Good for starting the conversation

➢ Closed (Yes/No or other specific answers):  Good for getting specific answers

➢ Clarifying:  Used to summarize what the auditee has just said in order to verify you've got it right

➢ Leading questions:  Use in moderation.  If the auditee is confused (maybe about terminology) it's sometimes ok to lead them to the answer you are looking for. (Example:  Auditor:  "Can you tell me about our Quality Policy?"  Auditee:  Silence and blank stare.  Auditor:  "Joe, we call that our mission statement.

Can you explain that?"  Auditee:  "Oh!  Sure.")

**PEARS – What are they? Who does it and how?**

Identifying and Understanding **P**rocess **E**ffectiveness **A**ssessment **R**eports (**PEAR**'s) using Process Interaction Map, Key Processes, Key Process Identifier's (KPI's), and Turtles

# Process Effectiveness Assessment Report

➤ **The Registrar Auditor completes a PEAR but it works really well for your organization if you do internal audits using self identified Key Processes.**

➤ **The process owner must understand what the auditor expects to see.**

➤ **Some of the Key Process Identifiers "KPI's" should include the data needed to measure your companies Goals and Objectives as discussed in your Management Review.**

➤ **The Process Interaction Map in your quality manual *must* include the same processes as your PEARS.**

➤ **Some of the Key Process Identifiers "KPI's" should include the data needed to measure your companies Goals and Objectives as discussed in your Management Review.**

# Identifying Key Processes

➢ A KEY PROCESSES are those processes that have maximum impact on the success of an organization.

  ➢ they deliver results that are directed toward specific and measureable business goals,

  ➢ they ensure that your organization remains competitive.

  ➢ they are the real value creating processes in the organization that the stakeholders are interested in.

➢ Step 1: Identify critical success factors (CSFs) to achieve the companies objectives

➢ Step 2: Identify metrics for measuring the critical success factors (these are your KPIs)

➢ Step 3: Identify the processes that deliver the above drivers or KPIs

# Turtle Diagram – Illustrate your Key Processes
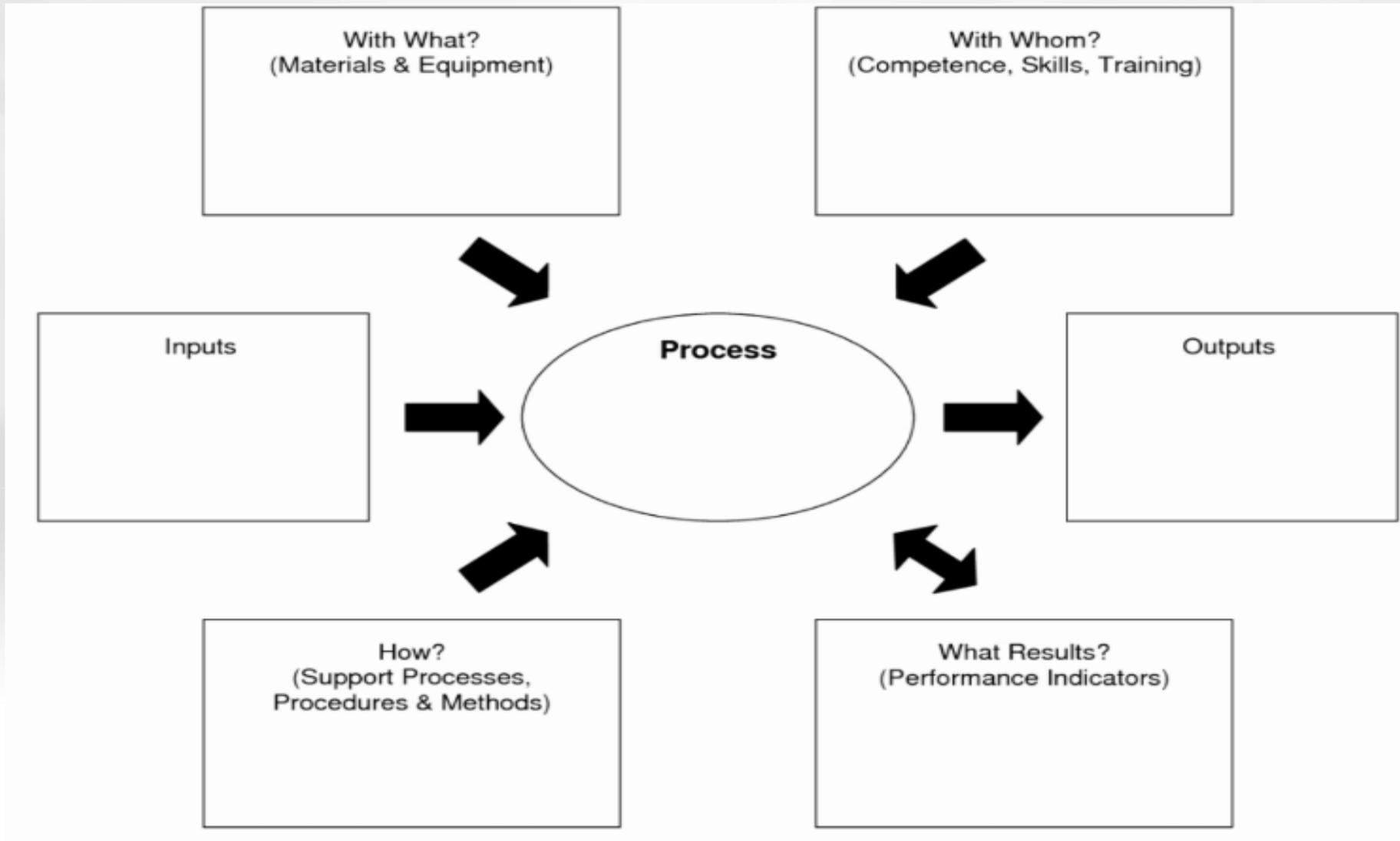
## What Are "Measures"?

The measures of a process include your "Key Performance Indicators or KPI's". These are the data collected to ensure your process is stable and achieving the desired results (outputs). This can include inspection data, returns data, failure analysis, etc.

3 Types of Process Measures:

➢ Internal Measures

➢ Output Measures

➢ Satisfaction Measures

# Characteristics of Good KPI's

They are the leading indicators of performance desired by the organization.

- KPI's are always connected with the corporate goals (objectives).
- KPI's are decided by the management.

A KPI needs to be:

- Specific
- Measurable
- Achievable
- Result-oriented
- Relevant
- Time-bound
- Easy to understand at all levels

Which Measures (Metric) to Choose?

## Which Measures (Metric) to Choose?

➢ Does the measure provide information that is useful in understanding and improving the process?

➢ Can the measure be easily understood by others who have a working understanding of the process?

➢ Is the data for the measure available and can be gathered with little difficulty?

➢ Consider the following:

- Define what data will be required for the specific metric

- Define how the data will be collected

- Define who will collect the data

- Define who will analyze the data

- Define what you will do with the results

- Define what will happen if the desired results are not achieved.

# What is an "Input"

- **Inputs** are the items you have to consider when implementing a process? The most common Inputs are internal *and* external Customer Requirements.

- Other inputs to consider are any regulatory requirements and your own internal requirements as defined by your QMS procedures.

# Determine With Whom, What and How?

| With Whom? | "With whom" is simply asking what people do you need to achieve the planned results? What competency, skills, experience, education etc. It is okay to simply list a job title here. |
|---|---|
| With What? | With what asks you to consider and document any Material and Equipment used such as ERP system, Sharepoint, Machines, Inspection Tools, Test Equipment, Software, Computers etc. This will vary depending on the process. |
| How? | How is asking you to document which directions or processes you use to achieve the desired results such as your internal processes, guidelines, forms, methods, Statement of Work, Contractual requirements etc. |

# What are the "outputs"

- What are the desired results you are trying to achieve?

- What are the items or things that your process is producing and who do you send it to?

- This can be either internal and external output. A widget, report, service, or a partial widget that gets sent to the next stage in the process are all acceptable "outputs".

- For any process, the output should represent the satisfaction of Customer Requirements.

What Now?

# Assessment

Auditors examine the data points and will assess if the process is in control by ensuring the KPIs are met

In order to be assesses as effective a process should score a 3 – 5 meaning if for whatever reason you do not meet your Goals / KPIS's you must have taken measures to correct

A score or 1-2 will greatly impede obtaining registration and will, at a minimum require additional follow ups to ensure a stable / effective process

# Audit Phases

- **Audit Wrap Up: Closing Meeting, who should attend, what is discussed**

- **Audit Report Writing: Report Completion, Corrective Action Documentation**

- **Corrective Action Follow Up and Closure**

# Corrective Action Using the "5 why" technique to get to the True Root Cause

**#1 Ensure the ROOT CAUSE sounds viable and specific to the issue at hand**

**ROOT CAUSE =**

- The causal or contributing factors that, if corrected, would prevent recurrence of the identified problem

- The "factor" that caused a problem or defect and should be permanently eliminated through process improvement

- The "factor" that sets in motion the cause and effect chain that creates a problem

- The "true" reason that contributed to the creation of a problem, defect or nonconformance

# Human Factors – Dirty Dozen As Developed by FAA SAFETY.GOV

## Human Factors – *The Dirty Dozen*

Communication

Awareness

Knowledge

Distraction

Stress | Fatigue

Resources Norms

Pressure

Teamwork

Complacency

Assertiveness

Daily Pressures

- Lack of communication
- Complacency
- Lack of knowledge
- Distractions
- Lack of teamwork
- Fatigue
- Lack of resources
- Pressure
- Lack of assertiveness
- Stress
- Lack of awareness
- Norms

# Root Cause Identification – Why is it so important?



"We are too busy" or
**Quick Fix APPROACH**

Problem Identified → **Firefighting!** Immediate Containment Action Implemented and problem resolves....for now → Problem recurs elsewhere!

"This cannot happen again" or
**PREFERRED APPROACH**

Problem Identified → Immediate Containment Action Implemented → Defined Root Cause Analysis Process → Solutions validated with data → Solutions are applied across company and never return!

# Root Cause – 5 Whys Preparation

**5 Whys is a root cause analysis tool, not a problem solving technique. The outcome of a 5 Whys analysis is one or several root causes that ultimately identify the reason why a problem was originated. There are other similar tools as the ones mentioned below that can be used simultaneously with the 5 Whys to enhance the thought process and analysis.**

| Problem | → | Root Cause | → | Corrective Actions |
|---------|---|------------|---|--------------------|
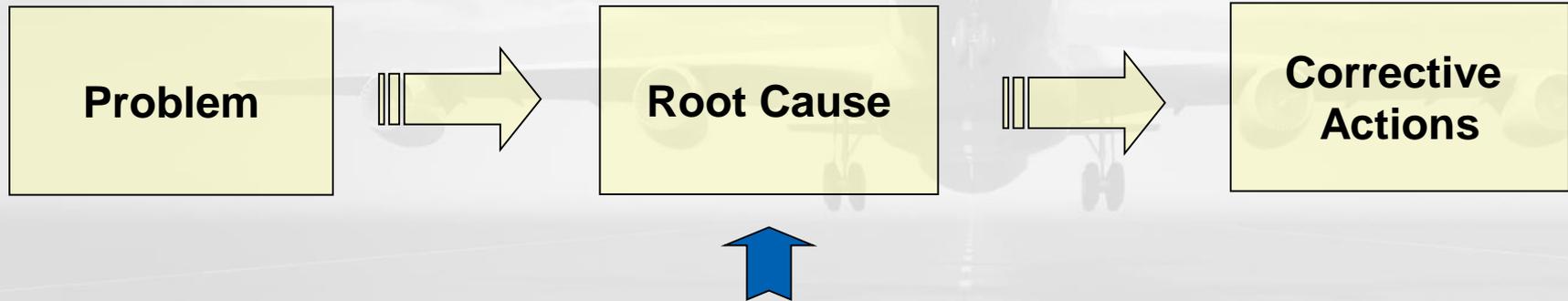
**Root Cause Analysis Tools:**
- Ishikawa Charts (Fish Bone)
- Design of Experiments
- Is / Is not Analysis
- **5 Whys**
- Cause & Effect Diagram.
- Statistical Data Analysis (Cpk, Pareto Charts, Anova, etc…)

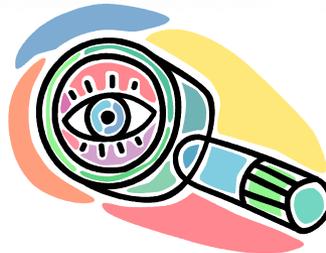# Root Cause – 5 Whys Preparation

- **Any 5 Whys must address two different problems at the same time. The first part is related to the process that made the nonconformance.**

**("Why happened?")**

- **The second one must address the detection system that was not able to detect the nonconformance before it became a problem. The lack of detection of a nonconformance is a problem of its own and must be treated independently than the nonconformance itself.**

**("Why not detected?")**

# Root Cause – 5 Whys Preparation

**Ask the full question including the problem or cause behind it. If there is a problem with labeling ask:**

- **"Why were the parts were labeled incorrectly?"**

**If the answer is <u>unreliable database</u> ask:**

- **"Why is the database unreliable?"**

**If we do not follow this approach answers to the whys tend to lose focus on the third or fourth why.**

# Root Cause – 5 Whys Preparation

- **Even though the discipline is called 5 Whys is _not always_ necessary to reach 5 before the root cause of a problem is fully explained; or it may take more than 5 whys to get to the bottom of it. It will depend on the complexity of the process or the problem itself.**

- **In any case, 5 has been determined, as a rule of thumb, as the number at which most root causes are clearly identified. Do not worry about not meeting or exceeding this number though. Just follow your thought process and let it decide how many whys you require to get to the point where the root cause is evident.**

# Follow Up and Closure

➢ Follow the same process to follow up on answered Corrective Actions.
➢ Make Sure they addressed the issue for which the Corrective Action was issued
➢ Ensure they got to the true root cause
➢ Ensure they looked at similar processes for similar issues
➢ If they trained employees – interview those employees to ensure the training was effective
➢ If they revised a process – ensure the changes have been implements
➢ Follow up **AGAIN** during the next scheduled audit to ensure the corrections are still in place

## **TRUST BUT VERIFY – EVERY TIME, EVERYONE**

# What Did We Learn?
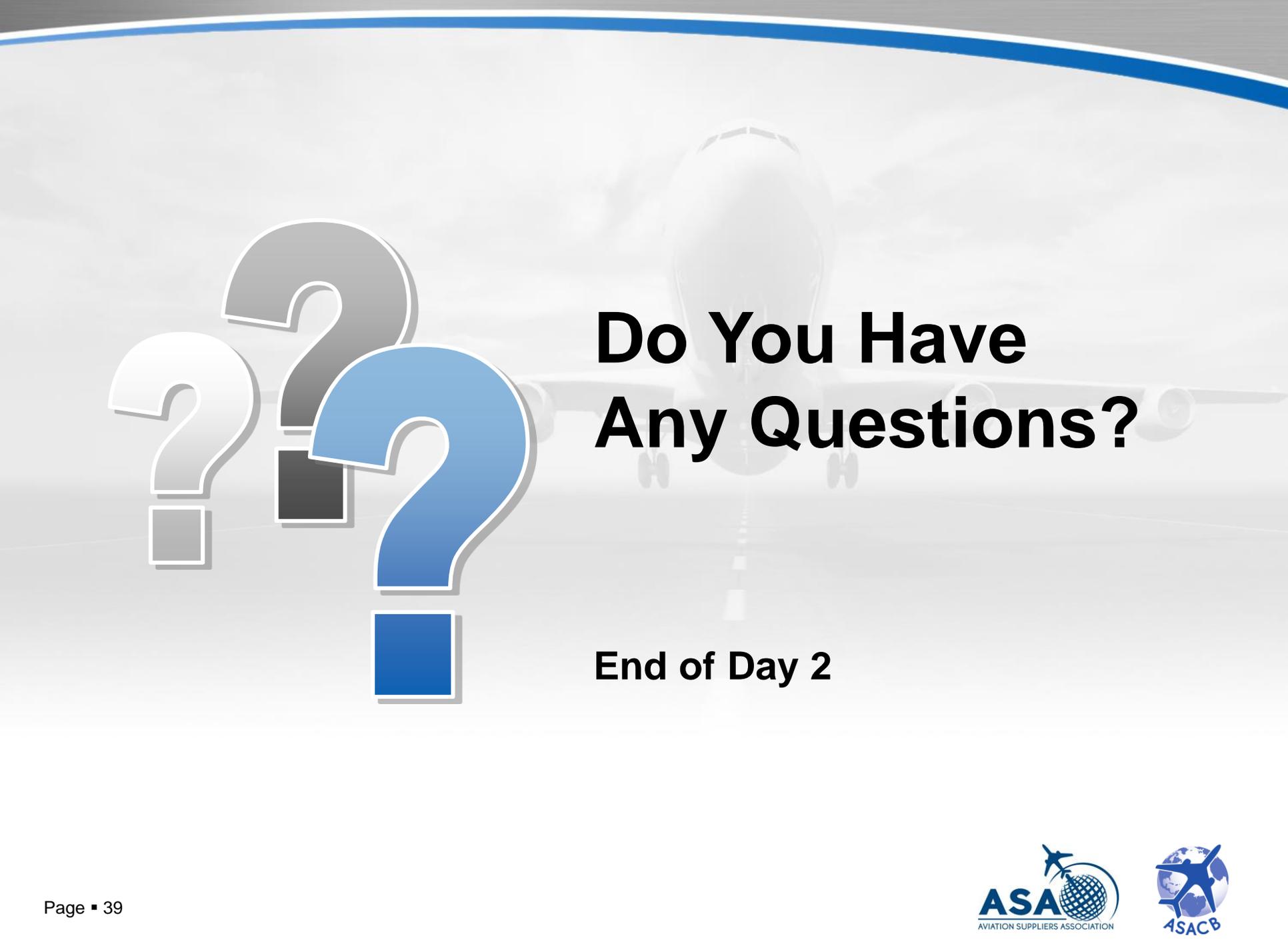
# Do You Have Any Questions?

**End of Day 2**